SYNTHES®

MAY 2 3 2001

K010518

3.0 Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Thomas M. Maguire
DEVICE NAME:	Synthes Anterolateral Calcaneal Plate
CLASSIFICATION:	Class II, 21 CFR 888.3030: Single/multiple component bone fixation appliances and accessories.
PREDICATE DEVICE:	Synthes Multiple Fragment Plate
DEVICE DESCRIPTION:	The Synthes Anterolateral Calcaneal Plate is a low profile plate used to fix intra-articular fractures of the calcaneus. The plate has five holes and can be contoured as needed to fit the specific anatomy and to fit under the anterior facet. The plate has a symmetrical design so that it can be used on both the right and left calcaneus. The low profile feature is intended to minimize soft tissue irritation.
INTENDED USE:	The Synthes Anterolateral Calcaneal Plate is intended for intra-articular fractures of the calcaneus, including joint depression, nondisplaced, and tongue type. The plate is used to laterally reduce the anterior fragments of these fractures about the primary fracture line emanating from the anterior facet.
MATERIAL:	316L Stainless Steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2001

Mr. Thomas M. Maguire
Project Leader, Regulatory Affairs
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K010518
Trade Name: Synthes Anterolateral Calcaneal Plate
Regulation Number: 888.3030
Regulatory Class: Class II
Product Code: KTT
Dated: February 21, 2001
Received: February 22, 2001

Dear Mr. Maguire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K010518

Device Name: Synthes (USA) Anterolateral Calcaneal Plate

Indications/Contraindications: The Synthes Anterolateral Calcaneal Plate is intended for intra-articular fractures of the calcaneus, including joint depression, nondisplaced, and tongue type. The plate is used to laterally reduce the anterior fragments of these fractures about the primary fracture line emanating from the anterior facet.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_
(Per 21 CFR 801.109)

for Mark N. Milhan
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010518